REMARKS

Claims 1, 12, 13, 21, 24, 25, 29, 31 and 39-60 are pending. Claims 1, 42, 43, and 60 have been amended herein for clarity. Support for these amendments may be found in the application as originally filed. In particular, the amendments being made have support in the original claims or are merely correcting grammatical or typographical errors. Accordingly, no new matter is added by the amendments to the claims.

The Claim Objections Are Rendered Moot

Claim 1 was objected to based on the presence of an extra comma after "I47V" and based on the phrase "whether the protease encoded by said HIV-1 exhibits." Applicants have deleted the extra comma as well as the objected to phrase. Therefore, this objection is moot, and Applicants respectfully request that it be withdrawn.

Claims 42 and 60 were objected to as having grammatical errors. In particular, the Office Action noted that the word "mutation" in the singular form does not agree with the multiple amino acid positions listed. In addition, Claim 42 was objected to as containing extra commas. Applicants have amended Claim 42 to delete the objected to commas. Applicants also have amended Claims 42 and 60 to clarify that the methods involve detecting the presence or absence of a mutation "at each one of" the amino acid positions. Therefore, these objections are moot, and Applicants respectfully request that they be withdrawn.

The Rejection of the Claims Under 35 U.S.C. 102(b) Is Traversed or Rendered Moot

Claims 1, 12, 13, 21, 24, 25, 29, 31, and 39-60 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Carrillo *et al.* (1998, *J. Virol.* 72(9):7532-41) (hereinafter "Carrillo"). Applicants respectfully submit that the pending claims as amended are not anticipated by the teachings of Carrillo.

The Office Action asserted that Carrillo teaches the detection of mutations in the HIV-1 protease gene after treatment with a protease inhibitor. The Office Action noted that the mutations identified in Carrillo are L33I, E34A, E34K, A71V, L76V, V82A, and T91S when compared to the sequence of a wild type NL4-3 strain protease. The Office

Action also asserted that the teachings of Carrillo inherently anticipate the claims because the phrases "for determining whether a HIV-1 has an increased likelihood of having a reduced susceptibility to treatment with amprenavir," "associated with reduced susceptibility to treatment with said protease inhibitor," and "wherein the presence of said mutation indicates that the HIV-1 has an increase in likelihood of having reduced susceptibility to treatment with amprenavir" are only intended uses and newly discovered properties of the prior art methods disclosed in Carrillo.

Applicants have amended Claim 1 to recite the active step of "determining whether the HIV-1 has an increased likelihood of having a reduced susceptibility to treatment with amprenavir, wherein the presence of said mutation indicates that the HIV-1 has an increased likelihood of having a reduced susceptibility to treatment with amprenavir." Therefore, the reduced susceptibility is not just an intended use, but rather is an active step.

A claim is anticipated only when a single prior art reference discloses each and every element set forth in the claim. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicants respectfully submit that Carrillo does not teach each and every element of the pending claims. Applicants note that Carrillo teaches that the disclosed amino acid substitutions in the protease result in increased resistance to the protease inhibitor **ABT-378** (Abstract). Carrillo does not teach or remotely suggest that the disclosed amino acid substitutions would confer reduced susceptibility to **amprenavir**. Moreover, one of skill in the art would not expect that the presence of the same or a different mutation at the same amino acid position of the protease gene that confers increased susceptibility to one protease inhibitor (*e.g.*, ABT-378) would also confer susceptibility to a different protease inhibitor (*e.g.*, amprenavir). In fact, the relevant art actually teaches away from such an expectation.

For example, Collonno *et al.* (2004, *J. Infect. Dis.* 189:1802-10) teach that a substitution of two different amino acids at the same amino acid position does not result in similar resistance properties. Collonno *et al.* teach that a substitution of leucine for isoleucine at position 50 of the protease gene reduces susceptibility to one protease inhibitor (*i.e.*, atazanavir), and increases susceptibility to another protease inhibitor (*i.e.*, amprenavir) (page 1808, Table 4). In addition, a different amino acid substitution at the

same position has a different effect. A substitution of valine instead at position 50 actually confers reduced susceptibilty to amprenavir and increased susceptibility to atazanavir. Therefore, Collono *et al.* clearly teach that a single amino acid substitution can have dramatically different effects with respect to two different protease inhibitors. Collono *et al.* also teach that two different amino acid substitutions at the same amino acid position can have very different impacts on protease inhibitor susceptibilitiy.

Similarly, Hirsch *et al.* (2008, Clin. Infect. Dis. 47:266-85) teach that resistance may be more complicated than identifying a single mutation. In particular, Hirsch *et al.* provide a table showing the complexity of resistance mutation profiles, clearly showing that knowledge of the position of a single mutation is not enough to predict resistance to a protease inhibitor. Rather, it is patterns of mutations that are important with respect to protease inhibitor resistance, and not single mutations alone (page 267, Figure 1).

Carrillo does not teach each and every element of the pending claims as amended because Carrillo does not teach or remotely suggest that the disclosed mutations would affect susceptibility to amprenavir. Accordingly, Carrillo does not anticipate the pending claims as amended, and Applicants respectfully request the rejections under 35 U.S.C. § 102 be withdrawn.

CONCLUSION

Applicants submit that the foregoing is a full and complete response to the Final Office Action mailed February 4, 2010. In view of the foregoing amendment and remarks, each of the claims remaining in the application is in condition for immediate allowance. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the outstanding rejections.

If the Examiner believes that any informalities remain in the case that may be corrected by Examiner's Amendment, the Examiner is respectfully invited to telephone the undersigned attorney at (404) 541-6662 or Dr. Cynthia B. Rothschild at (336) 747-7541 to discuss any questions relating to the application.

Applicants have submitted herewith a petition for a two month extension of time, along with the appropriate fee therefore. No additional fees are believed due; however the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account number 11-0855.

Respectfully submitted,

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